

**NOT FOR PUBLICATION**

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

HOFFMANN-LA ROCHE INC.,	:	
Plaintiff,	:	Civil Action No. 07-4417 (SRC) (MAS)
v.	:	Civil Action No. 08-3065 (SRC) (MAS)
APOTEX INC. and APOTEX CORP.,	:	Civil Action No. 08-4053 (SRC) (MAS)
Defendants.	:	(consolidated with 07-4417 for all purposes)
		<b>OPINION</b>
HOFFMANN-LA ROCHE INC.,	:	
Plaintiff,	:	Civil Action No. 07-4539 (SRC) (MAS)
v.	:	Civil Action No. 07-4540 (SRC) (MAS)
COBALT PHARMACEUTICALS INC.,	:	Civil Action No. 08-4054 (SRC) (MAS)
and COBALT LABORATORIES, INC.,	:	(consolidated with 07-4539 for all purposes)
Defendants.	:	

**CHESLER, U.S.D.J.**

This matter comes before the Court on two motions for summary judgment, pursuant to Federal Rule of Civil Procedure 56: 1) the motion for summary judgment of no inequitable conduct as to the '814 patent by Plaintiff Hoffman-La Roche Inc. ("Roche"), against Defendants Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc. (collectively, "Cobalt") and Apotex Inc. and Apotex Corp. (collectively, "Apotex"); and 2) the motion for summary judgment, by Apotex, that the 4,927,814 patent is unenforceable based on inequitable conduct. For the reasons stated below, both motions will be denied.

## **BACKGROUND**

This matter involves several Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Roche owns U.S. Patent No. 4,927,814 (the “‘814 patent”), which is directed to certain disphosphonate compounds, pharmaceutical compositions and methods of use of same, and which includes ibandronic acid, the active ingredient in Roche’s osteoporosis drug Boniva®. Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of Roche’s patent.

Defendants have answered Roche’s claim of infringement of the ‘814 patent with the affirmative defense that the patent is unenforceable due to inequitable conduct. Now before the Court are two summary judgment motions on this affirmative defense, Roche’s motion for summary judgment of no inequitable conduct, and Apotex’s motion for summary judgment of inequitable conduct.

## **ANALYSIS**

### **I. Relevant legal standards**

#### **A. Motions for summary judgment**

Summary judgment is appropriate under FED. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party’s entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of

the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). “In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence ‘is to be believed and all justifiable inferences are to be drawn in his favor.’” Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

“When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party.” In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). “[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by ‘showing’ – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party’s case.” Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). “[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment.” Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990); see also FED. R. CIV. P. 56(e) (requiring

nonmoving party to “set out specific facts showing a genuine issue for trial”). “A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial.” Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed “to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will bear the burden of proof at trial, . . . there can be ‘no genuine issue of material fact,’ since a complete failure of proof concerning an essential element of the nonmoving party’s case necessarily renders all other facts immaterial.” Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

B. Inequitable conduct

“A patent may be rendered unenforceable due to inequitable conduct if an applicant, with intent to mislead or deceive the examiner, fails to disclose material information or submits materially false information to the PTO during prosecution.” Golden Hour Data Sys. v. emsCharts, Inc., 2010 U.S. App. LEXIS 16455 (Fed. Cir. Aug. 9, 2010) The Federal Circuit has summarized the fundamental principles for deciding whether a patent should be found to be unenforceable due to inequitable conduct as follows:

Patent applicants and those substantively involved in the preparation or prosecution of a patent application owe a “duty of candor and good faith” to the PTO. 37 C.F.R. § 1.56(a) (2004). A breach of this duty may constitute inequitable conduct, which can arise from a failure to disclose information material to patentability, coupled with an intent to deceive the PTO. Both of these elements, intent and materiality, must be proven by clear and convincing evidence. . . Although it is not impermissible to grant summary judgment of inequitable conduct, this court urges caution in making an inequitable conduct determination at the summary judgment stage.

M. Eagles Tool Warehouse, Inc. v. Fisher Tooling Co., 439 F.3d 1335, 1339-1340 (Fed. Cir. 2006) (citations omitted). “Upon finding evidence that satisfies a threshold measure of materiality and intent, the trial court then weighs that evidence to determine that the equities warrant a conclusion of inequitable conduct.” Agfa Corp. v. Creo Prods., 451 F.3d 1366, 1377 (Fed. Cir. 2006).

## **II. Roche’s motion for summary judgment of no inequitable conduct**

Roche moves for summary judgment on the affirmative defense that the ’814 patent is unenforceable due to inequitable conduct, seeking a summary judgment of no inequitable conduct. Roche begins by noting that Cobalt and Apotex, between them, make eighteen specific allegations of omission of material information or material misstatements. Roche then states its argument succinctly: “Cobalt and Apotex lack evidence to establish intent to deceive as to each of their 18 allegations.” (Pl.’s Br. 3.) Since, at trial, Cobalt and Apotex bear the burden of proof of their affirmative defenses, the summary judgment burden now shifts to them to point to evidence sufficient for a jury to find in their favor on the intent element at trial.

The briefs by Cobalt and Apotex build their case by discussing the allegations of omission of material information and material misstatements. Cobalt contends that Roche errs when it asks the Court to consider each alleged misrepresentation or omission individually, and argues that, when the instances are viewed together, the finder of fact will find intent to deceive.

Roche’s motion for summary judgment must be denied because many of the allegations involve complex sets of disputed facts and require fact-intensive inquiries. Consider, for example, the very first item that both Apotex and Cobalt discuss: the alleged misrepresentation of data for the Example 6 compound in the declaration submitted to the PTO by the applicant to

overcome an obviousness rejection (the “Bosies Declaration.”) The parties agree that the Bosies Declaration contained a table with an error in its presentation of data for the compound of Example 6, such that the number is wrong by a factor of 10. Roche contends that this is a mere “typo;” Defendants contend that it is the result of a deliberate attempt to deceive the PTO by exaggerating the performance of the compound to be patented relative to the prior art. This determination goes to the heart of the issue of intent, and a reasonable jury could easily agree with either party; this kind of determination must be made by a jury.<sup>1</sup> This is a dispute over a material fact and, as such, the issue of intent cannot be resolved on summary judgment.

Consider also one key theory that Apotex advances, built on a number of similar determinations. Apotex contends that the Bosies Declaration failed to disclose data for Examples 12 and 14 and overstated results for Examples 9A and 9B. Consider first the inquiry into the most basic facts. While Roche agrees that the Bosies Declaration did not disclose data for Examples 12 and 14, Roche disputes that the results for Examples 9A and 9B were overstated. This alone raises a material factual dispute.

“But,” to quote Cobalt, “there’s more.” (Cobalt’s Opp. Br. 13.) Apotex builds on these alleged omissions and misrepresentations and contends that they all serve to support the proposition that the claimed compound had greater effectiveness than prior art compounds, and they all helped the applicant overcome the obviousness rejection. Apotex argues that, when all these pieces are viewed together, there is a “pattern of misleading activity.” (Apotex’s Opp. Br.

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<sup>1</sup> Cobalt argues that Dr. Bosies’ assertion that this is a “typo” is not credible. (Cobalt’s Opp. Br. 27.) Credibility determinations are uniquely the province of the finder of fact. A jury will need to observe Dr. Bosies testifying, and watch him being cross-examined, in order to make this determination.

39.) Roche agrees that the Bosies Declaration was submitted to the PTO to overcome an obviousness rejection, but disagrees that anything was misleading.

If Apotex convinced a jury as to its view of the various component omissions and misrepresentations, it would have a fair shot at persuading a jury that these components, when viewed together, constitute a pattern of misleading activity, and that such a pattern is clear and convincing evidence of the applicant's intent to deceive the PTO. And Roche has a fair shot at persuading a jury that this is all much ado about nothing. A jury must decide.

This Court, on this record, is simply not in a position to conclude that Defendants cannot meet their burden of demonstrating by clear and convincing evidence that the applicant's submissions to the PTO were made with deceptive intent – even in light of the Federal Circuit's statement in Star Sci., Inc. v. R.J. Reynolds Tobacco Co. that “the inference [of deceptive intent] must not only be based on sufficient evidence and be reasonable in light of that evidence, but it must also be the single most reasonable inference able to be drawn from the evidence to meet the clear and convincing standard.” 537 F.3d 1357, 1366 (Fed. Cir. 2008). Issues of intent are rarely amenable to resolution on summary judgment. Louis Schelsinger Co. v. Kresge Foundation, 388 F.2d 208, 212 (3d Cir. 1968).

Material factual disputes preclude the entry of judgment as a matter of law. Roche's motion for summary judgment will be denied.

### **III. Apotex's motion for summary judgment of inequitable conduct**

Apotex moves for summary judgment on the affirmative defense that the '814 patent is unenforceable due to inequitable conduct, seeking a summary judgment of inequitable conduct. Roche opposes the motion on two grounds: 1) disputed factual issues concerning the materiality

of the alleged mischaracterizations or omissions preclude the entry of judgment as a matter of law; and 2) Apotex has no evidence of specific intent to deceive the PTO.

Apotex first argues, as mentioned above, that the applicant engaged in inequitable conduct by submitting to the PTO the Bosies Declaration, which failed to report the test results for Examples 12 and 14. In opposition, Roche points to the report of its expert, Mr. Killworth, which asserts that data for Examples 12 and 14 was not material because these compounds were not members of the set of lower homologues of prior art references that the examiner had cited. (Borchetta Dec. Ex. LL ¶ 103.) In reply, Apotex calls Killworth's opinion "unsupported," but provides no further explanation. While this Court queries whether an expert on PTO procedures is qualified to offer an expert opinion on what appears to be a matter of chemistry, this Court also takes note that Apotex has not argued that Killworth is incorrect in stating that Examples 12 and 14 are not homologues of the prior art compounds of interest. This Court finds that the Killworth report is sufficient at this juncture to raise a factual dispute over the materiality of the omission of data for Examples 12 and 14 from the Bosies Declaration.

There is at least one factual dispute which precludes the entry of judgment as a matter of law on Apotex's affirmative defense of inequitable conduct. Apotex's motion for summary judgment will be denied.

**CONCLUSION**

For the reasons stated above, this Court finds that material factual disputes preclude any grant of summary judgment; neither party has shown that it is entitled to judgment as a matter of law. Both Roche's motion for summary judgment of no inequitable conduct and Apotex's motion for summary judgement of inequitable conduct are denied.

s/ Stanley R. Chesler  
Stanley R. Chesler, U.S.D.J.

Dated: September 30, 2010